

**510(k) Summary**

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JUN 22 2010

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Date of Summary: May 14, 2010

Classification Name: Endosseous Dental Implant Abutment  
Classification Number: 872.3630  
Product Code: NHA  
Trade Name: Talladium International Implantology Abutments  
510(k) Number: K090081

**Legally Marketed Predicate Devices**

External Hexagon abutments, e.g., K032263, K925769  
Conical abutments, e.g., K990342, K041295, K072570  
Internal Conical abutments, e.g., K020096, K060880, K071439  
Internal abutments, e.g., K053355, K073345

**Device Description**

The Talladium abutments are an artificial tooth abutment designed to fit and function on root-form endosseous implants having various abutment interfaces: an external hexagon, conical, internal conical, and other internal connections such as multi-lobed. Talladium also has a dynamic abutment to correct the angulation of an implant if necessary.

Talladium's abutments are intended for use in the treatment of partially edentulous patients in order to restore chewing function. The Talladium abutments are prosthetic abutments that fit a variety of endosseous implants listed below. Talladium's abutments are made from tilite, a biocompatible Base Metal Alloy material that is used in dental restorations.

**Indication for Use/Intended Use**

Talladium abutments are used in connection with the prosthetic restoration of dental implants. Abutments are intended to be placed into dental implants to provide support for prosthetic reconstructions such as crowns and bridges. The Talladium abutments fit implants with external hexagon, conical, internal conical, and other internal (e.g., multi-lobed) implants. A dynamic abutment is available to correct the angulation of an implant if necessary (limiting the angulation of the dynamic abutments to 20° off of the long axis of the implant).

The Talladium abutments have been tested with the following implant systems:

- Group 1, External Hexagon Abutments: 3i Implant Innovations, Biomet
- Group 2, Conical Abutments: Nobel Biocare Multi-Unit
- Group 3, Internal Conical Abutments: Zimmer Screw-Vent SD
- Group 4, Internal Abutments: Nobel Biocare Replace RP

Talladium abutments are compatible with the following implants: 3i Implant Innovations Biomet, Innova, Life-Core, Nobel Biocare, Implamed, Zimmer, IMZ, Bti, Klockner *external hexagon implants*; Straumann and Nobel Biocare *conical implants*; Zimmer, BioHorizons and Blue Sky Bio *internal hexagonal implants*; and Nobel Biocare and Blue Sky Bio Trilobe platform *internal connections*.

### **Performance Standards**

The Class II Special Controls Guidance Document: Root-Form Endosseous Dental Implants and Endosseous Dental Implant Abutments; Guidance for Industry and FDA Staff (May 12, 2004) was followed as applicable to this submission. Performance (fatigue) testing according to ISO 14801:2007<sup>1</sup> has ensured the appropriate design of the Talladium devices.

### **Non-Clinical Performance Data**

Static and dynamic tests of compression bending were performed for four dental abutment and implant systems, one (the most susceptible) for each type of connection, according to ISO 14801:2007, including the dynamic abutment. All testing passed the acceptance criteria. In addition, scanning electron microscopy (SEM) was performed to examine particle formation of tested pieces. In all cases, SEM testing showed negligible to moderate wear, and wear was comparable or less severe than in similar studies.

The Talladium abutments are composed of tilite with titanium alloy. Biocompatibility of this biomaterial has previously been cleared by FDA for use in fixed prosthodontic devices with tissue contact similar to that of the Talladium abutments.

### **Basis for Substantial Equivalence**

The Talladium Abutments are substantially equivalent in terms of intended use, design, and performance to the predicate devices (see next page). The exact configuration of currently marketed abutments is duplicated in the Talladium abutment series, and non-clinical performance testing (fatigue testing and biocompatibility) was used to validate that performance was acceptable for intended use. Taken together, these factors support the substantial equivalence of Talladium abutments to the predicate devices.

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<sup>1</sup> ISO 14801:2007. Dentistry – Implants – Dynamic Fatigue Testing for Endosseous Dental Implants.

# SUBSTANTIAL EQUIVALENCE TABLE

CATEGORY, 510(k) NUMBER	TRADE NAME, MANUFACTURER	DESCRIPTION	SIMILARITIES	DIFFERENCES	SIGNIFICANCE OF DIFFERENCE
External Hexagon K032263	3i Patient-Specific Dental Abutment and Overdenture Bar, Implant Innovations Inc. DZE	Series of dental abutments and overdenture bars	Talladium 3i-type abutments are the same shape, design and use as K032263	No overdenture bars in current 510(k), material not known	None
External Hexagon K925769	Branemark System Abutments Complete, Nobelpharma DZE	Series of abutments	Talladium Branemark-type abutments are the same shape, design and use as K925769	Material not known	Talladium material and fatigue testing shows acceptable performance
Conical K990342	Synocta Prosthesis, Straumann DZE	Series of abutments, and other components	Titanium alloy and other materials	Some materials different	Talladium material and fatigue testing shows acceptable performance
Conical K041295	RN Synocta UCLA Gold Abutment for the Straumann Dental Implant, Institut Straumann AG NHA	Series of abutments	Talladium Straumann-type abutments are the same shape, design and use as K041295	Material not reported	Talladium material and fatigue testing shows acceptable performance
Conical K072570	Nobelactive Multiunit Abutment, Nobel Biocare AB NHA	Abutment	Talladium Nobel Biocare-type abutments are the same shape, design and use as K072570	Material not known	Talladium material and fatigue testing shows acceptable performance
Internal Conical K020096	Esthetic Ease Abutments for the ITI Dental Implant System, Institut Straumann AG DZE	System of implants, abutments, surgical parts, and instruments Material: Titanium	Talladium Straumann-type abutments are the same shape, design and use as K020096	Different material; no implants in current 510(k)	Acceptable change because material successfully tested for biocompatibility, fatigue and particle formation
Internal Conical K060880	Zimmer Dental One Piece Tapered Abutment, Models TAC1, TACW1,	Zimmer tapered abutments	Talladium Zimmer-type abutments are the same shape, design and use as K060880	None	None

CATEGORY, 510(k) NUMBER	TRADE NAME, MANUFACTURER	DESCRIPTION	SIMILARITIES	DIFFERENCES	SIGNIFICANCE OF DIFFERENCE
Internal Conical K071439	TA5C1, Zimmer Dental Inc.	System of abutments	Titanium alloy, called "patient-specific"	None known	Talladium material and fatigue testing shows acceptable performance
Internal Abutments K053355	Zimmer Patient-Specific Abutment, Internal Hex, Titanium, Zimmer Dental Inc. DZE	System of implants and abutments	Talladium BTI-type abutments are the same shape, design and use as K053355	Material not reported, no implants in current 510(k)	Talladium material and fatigue testing shows acceptable performance
Internal Abutments K073345	BTI Interna Dental Implant System, BTI Biotechnology Institute, SL DZE	System of Biomet 3i Certain abutments	Talladium Biomet 3i- type abutments are the same shape, design and use as K073345	Different material (ceramic)	Acceptable change because material successfully tested for biocompatibility, fatigue and particle formation



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Room - WO66-G609  
Silver Spring, MD 20993-0002

Talladium Europe S.L.  
C/O Ms. Diane Horwitz  
Mandell Horwitz Consulting LLC  
2995 Steven Martin Drive  
Fairfax, Virginia 22031

JUN 22 2010

Re: K090081

Trade/Device Name: Talladium International Implantology Abutments  
Regulation Number: 21 CFR 872.3630  
Regulation Name: Endosseous Dental Implant Abutment  
Regulatory Class: II  
Product Code: NHA  
Dated: June 11, 2010  
Received: June 16, 2010

Dear Ms. Horwitz:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

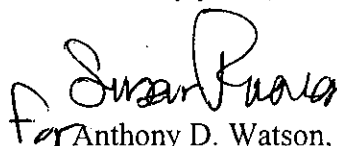
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



For Anthony D. Watson, B.S., M.S., M.B.A.

Director

Division of Anesthesiology, General Hospital,

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

K090081

## Indications for Use

510(k) Number (if known): K090081

Device Name: Talladium International Implantology Abutments

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Prescription Use   X    
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE  
IF NEEDED)

  
(Division Sign-Off)

Division of Anesthesiology, General Hospital  
Infection Control, Dental Devices

510(k) Number:   K090081  

Concurrence of CDRH, Office of Device Evaluation (ODE)